

REMARKS

Rejected claim 2 has been cancelled without prejudice, and new dependent claim 13 has been added to provide the scope and breadth of claims coverage to which Applicant is submitted to be entitled in view of the cited art.

Claims 1, 6 and 10 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Horzewski '588. This rejection is respectfully traversed with respect to these claims as amended herein.

Claim 1 specifically recites “an outer expandable sheath disposed about the inner cannula and including first and second shells adjacently aligned along longitudinal edges thereof to expand in an outward direction responsive to the tip of the inner cannula slidably passing longitudinally through the sheath.”

In addition, the dependent claims are further limited by specific recitations of “the inner cannula and outer expandable sheath are separable to allow the outer expandable sheath to remain in place at a surgical site as the inner cannula and the tip attached thereto are withdrawn,” or “the tip is disposed on the inner cannula distally of the outer sheath, the tip further comprising a distal tapered end for dissecting tissue, a proximal tapered end, and an enlarged intermediate portion having an outer dimension greater than an inner dimension of the sheath for exerting lateral expansion force against the outer expandable sheath responsive to slidable passage of the tip longitudinally through the outer expandable sheath.”

And new dependent claim 13 is further limited by recitation of "the first and second shells are configured as substantially half cylindrical segments adjacently aligned along the longitudinal edges thereof."

These aspects of the claimed invention are not disclosed or even suggested by Horzewski '588 which relies upon a continuous elastic outer tube to be expanded by an inelastic tubular member that is radially expandable about a delivery channel along a split in one wall. There is no disclosure in this reference of individual shells aligned along adjacent longitudinal edges for forming an expandable outer sheath, in any manner resembling Applicant's claimed invention.

Nor is there any disclosure in this reference of resilient connector between first and second shells urging the longitudinal edges of the shells together.

Significantly, there is no tip shaped or positioned, as claimed, for dissecting tissue and for expanding the outer sheath as the tip passes through.

It is therefore respectfully submitted that claims 1, 6 and 10 as amended are not anticipated by, but instead are now patentably distinguishable along with new dependent claim 13 over the cited art.

Rejected claim 9 has been cancelled without prejudice.

Claims 4, 5, 7 and 8 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Horzewski '588 in view of Davis et al. '406. This rejection is respectfully traversed with respect to these claims as amended herein.

These dependent claims are further limited by such specific recitations as “a resilient connector attached between the first and second shells for resiliently urging the longitudinal edges of the shells together,” or “a retainer disposed near at least one of proximal and distal ends of the shells for retaining the shells against relative longitudinal movement,” or “an inner dimension at the distal end of the outer expandable sheath smaller than the outer dimension of the tip,” or “a second resilient connector disposed to resiliently urge a proximal end of the first shell toward a proximal end of the second shell to form an inner dimension at the proximal end of the outer expandable sheath smaller than the outer dimension of the tip.”

These aspects of the claimed invention are not disclosed or even suggested by the cited references considered either alone or in the combination proposed by the Examiner. Specifically, the deficient disclosure of Horzewski et al. ‘588, which relies upon a continuous elastic outer shell, is discussed in the above Remarks. And, Davis et al. ‘406 is noted to have laterally-expansive segments near a fixed distal tip, which segments are laterally expanded, not via passage of the tip therethrough, but by various actuators that are also disposed in approximately fixed positions proximally adjacent the fixed tip. At best, an outer tubular shell, or an inner push or pull rod actuates the relatively fixed, expansive segments. However, none of the cited references offers any hint of separable outer

expandable sheath from inner cannula, in any manner resembling Applicant's claimed invention, to facilitate retaining the outer sheath in tissue as the inner cannula is withdrawn from within the outer sheath.

Thus, merely combining the cited art in the manner as proposed by the Examiner fails to establish even a *prima facie* basis, including all recited elements, from which a proper determination of obviousness can be formed. It is therefore respectfully submitted that dependent claims 4, 5, 7 and 8 are now patentably distinguishable over the cited art.

Claims 4, 5, 7 and 8 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Horzewski et al. '588 in view of Gibson '789. This rejection is respectfully traversed with respect to these claims as amended herein.

Specifically, these dependent claims are further limited by such recitations as discussed in the above Remarks.

In contrast, neither Horzewski et al. '588 nor Gibson '789 disclose or even hint at expanding an outer sheath with a tip that is positionable forward or distally of the outer sheath and that expands the outer sheath in passing through it. At best, Horzewski et al. '588 is not understood to rely upon any such tip positioned for dissecting tissue as well as being capable of passing through the outer sheath to expand it. And, Gibson '789 relies upon a plunger D₂ to expand a continuous or homogeneous outer sheath, but not positionable distally of the outer sheath to

dissect tissue. At best, an outer tip of Gibson '789 is fixed at the distal end of the outer sheath and is not capable of passing through to expand the outer sheath.

Thus, merely combining the references as proposed by the Examiner at best would appear merely to yield a device having a fixed distal tip on an outer sheath that is not expanded by such fixed distal tip, in any manner resembling Applicant's claimed invention. Such combination of the cited references thus fails to establish even a *prima facie* basis, including all recited elements, from which a proper determination of obviousness can be formed. It is therefore respectfully submitted that dependent claims 4, 5, 7 and 8 as amended herein are now patentably distinguishable over the cited art.

Reconsideration and allowance of claims 1, 4-8, 10 and 13 over the cited art (including Guignard '517 and MacKenzie '777, cited but not applied) are solicited.

Entry of this amendment, which is submitted to condition this application for allowance, is requested. In the event rejection of a claim continues, it is requested

that this amendment be entered in order to simplify and clarify the issues for appeal.

Respectfully submitted,
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